JAN 2 4 2001

K003351

510(k) SUMMARY

SUBMITTED BY:

David M. Hooper, Ph.D.
Specialist, Regulatory and Clinical
Spinal Concepts, Inc.
12012 Technology Blvd., Suite 100
Austin, TX 78727

512-918-2700

October 25, 2000

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME
Classification name: Pedicle Screw Spinal System
Common/usual name: Posterior Spine Implants
Product classification: Class II
Proprietary name: ParsFix Cable-Screw System

PREDICATE DEVICE
The predicate devices are the existing Spinal Concepts, Inc. 5.0 millimeter pedicle screws, which are part of the BacFix® Ti Spinal Fixation System (approved under K983260 on October 21, 1998), and the Spinal Concepts, Inc. 1.0 millimeter titanium cable, which is included as part of the C-Fix™ Cable System (approved under K974020 on December 19, 1997).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

INDICATIONS FOR USE

The system is designed as an adjunct to the BacFix® Ti Spinal Fixation System and is intended to reduce pars defects and to stabilize the spinal operative site during fusion procedures. A spinous process grommet is included as part of the ParsFix Cable-Screw System. The grommet may be used with the cable-screw or for interspinous wiring. The system is designed as an adjunct to the BacFix® Ti Spinal Fixation System and is indicated for the following:

- Defect of pars lateralis
- Spondylolisthesis

The ParsFix Cable-Screw System is indicated for pedicle screw attachment for these indications between T1 and the sacrum.

DEVICE DESCRIPTION

The Spinal Concepts, Inc. ParsFix Cable-Screw System was designed for use with the BacFix® Ti Spinal Fixation System, which was originally granted marketing clearance via K973687 on March 18, 1998 and subsequently via K983260 on October 21, 1998.

The ParsFix Cable-Screw was developed to offer surgeons a means of reducing a defect in the pars lateralis. The ParsFix Cable-Screw is a pedicle screw integrated with a cable system. A cam/block interface is machined into the head of the pedicle screw. The ParsFix Cable-Screw is placed in the pedicle and a cable is passed through the cable block and around the spinous process (or through the spinous process grommet). This can be done unilaterally or bilaterally depending on the specific defect. The cable/s are then tightened with a cable tensioner. The cam lock, located in the head of the ParsFix screw, is turned with the supplied wrench and the cable is locked in place.

The ParsFix Cable-Screw is manufactured from titanium alloy (Ti 6Al 4V). The connector comes in screw diameters of 5.5 and 6.0 millimeters and lengths ranging from 30 to 70 millimeters.

The cable is made from the same titanium alloy, is 1.3 millimeters in diameter and comes in lengths of 24 and 30 inches (60.96 and 76.2 centimeters, respectively).

The spinous process grommet is made from the same titanium alloy, has an inner diameter of 3.28 millimeters and comes in three lengths. Lengths range from 3.4-10.2 mm to accommodate various thickness of the spinous process. The edges are beveled so that shear stress between the cable and grommet is reduced.

COMPARISON TO THE PREDICATE DEVICE

Substantial equivalence for the indications of the ParsFix Cable-Screw may be found by comparing it with its two predicate devices, the existing Spinal Concepts, Inc. 5.0 millimeter pedicle screws, which are part of the BacFix® Ti Spinal Fixation System, and the 1.0 millimeter titanium cable, which is included as part of the C-Fix™ Cable System. The 5.0-millimeter screws included in the BacFix® Ti Spinal Fixation System were granted marketing clearance via K983260 on October 21, 1998. The indications for use of this system are unchanged as the ParsFix Cable-Screw System is intended for spondylolisthesis caused by a defect in the pars lateralis. The C-Fix™ Cable System was originally granted market clearance via K974020 on December 19, 1997. Included in the indications for the C-Fix™ Cable System is the correction of spinal deformities including spondylolisthesis.

DISCUSSION OF NONCLINICAL TESTS

Mechanical testing was conducted on both predicate devices as part of their initial application for marketing approval. It can be concluded that the mechanical properties of the ParsFix Cable-Screw are greater than the 5.0 millimeter BacFix Ti System screw because the ParsFix Cable-Screw is proportionally larger than, and has the same screw profile, than the 5.0 millimeter BacFix Ti System screw. The cable/block on the head of

the screw will not affect the screw's ultimate strength or endurance limit. Similarly, the 1.3 mm cable is stronger than the 1.0 mm predicate which was previously cleared for the correction of spinal deformities. Mechanical testing of the spinous process grommet has shown that its resistance to disassembly is acceptable and that the beveled edges do not adversely affect the strength of the cable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2001

David M. Hooper, Ph.D.
Specialist, Regulatory and Clinical Affairs
Spinal Concepts, Inc.
12012 Technology Boulevard - #100
Austin, Texas 78727

Re: K003351
Trade Name: ParsFix Cable-Screw System
Regulatory Class: II
Product Code: KWP and DZK
Dated: October 25, 2000
Received: October 26, 2000

Dear Mr. Hooper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003351

Device Name: Spinal Concepts, Inc. ParsFix Cable-Screw System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

NRO for MW
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003351